REMARKS

Favorable consideration of this application is respectfully requested in view of the above amendment and the following remarks.

Claims 1-14 and 16 are pending claim in this application. Claims 1-14 and 16 have been rejected. Claims 1, 4, 6, 7, 10, 11 and 16 have been amended. Applicants submit that no new matter has been added.

Claims 1-14 and 16 have been rejected under 35 U.S.C. §112, first paragraph, based on alleged lack of enablement. The Examiner contends that the term "prodrug" in claim 1 is not adequately enabled.

In response, claim 1 has been amended to delete recitation of the term "prodrug".

In view of the above, withdrawal of the rejection of claims 1-14 and 16 under 35 U.S.C. §112, first paragraph, is respectfully requested.

Claims 1-14 and 16 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. In particular, the Examiner contends that the term "(CO)CH3" in the definition of R7 in claim 1 has insufficient antecedent basis. The Examiner also contends that the limitation "S and CH2" in the definition of X in claim 4 and the limitation "CH2" in the definition of X in claim 6 has insufficient antecedent basis. The Examiner also contends that the term "compounds" in claim and the moiety "ON" in claim 10 in the definition of R3 and/or R4 are vague and indefinite. The Examiner also contends that the limitation "S and NCH3" in the definition of X in claim 11 has insufficient antecedent basis.

In response, the term "(CO)CH3" in the definition of R7 in claim 1, the limitation "S and CH2" in the definition of X in claim 4, and the limitation "CH2" in the definition of X in claim 6, have been deleted. In addition, the term "compounds" in claim 7 has been amended to recite "compound" and the moiety "ON" in claim 10 in the definition of R3 and/or R4 has been deleted and replaced with the moiety "CN". Support for the amendment of "ON" to "CN" can be found in the specification, e.g., page 6, line 19. The limitation "S and NCH3" in the definition of X in claim 11 has also been deleted.

In view of the above, withdrawal of the rejection of claims 1-14 and 16 under 35 U.S.C. §112, second paragraph, is respectfully requested.

Claims 1-14 and 16 have been rejected under 35 U.S.C. §103(a) as being unpatentable over van der Burg, U.S. Patent Nos. 4,016,161 and 4,054,572 (the van der Burg patents). The Examiner contends *inter alia* that 1) the generic structure of van der Burg encompasses the instantly claimed compounds, 2) examples in column 15 of van der Burg are position isomers of the compounds of the present invention, and 3) compounds of formula I of the instant invention, differ only in the position of the moiety –(CH2)-N(R5)(R6). The Examiner also contends that the position of the moiety in van der Burg possesses the same level of activity as shown by the variability of the moiety on the piperidine ring of the tetracyclic ring system such that the moiety is substituted at the 2-position or 3-position of the ring system.Thus, the Examiner contends that one of ordinary skill in the art at the time the invention was made would have been motivated to select for example 1-dimethylamine NR6R7 as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above. The Examiner also contends that such modification would be obvious because such structurally related compounds suggest one another and would be expected to share common properties absent a showing of unexpected results. The Examiner also directs Applicants' attention to the claims of U.S Patent No. 4,061,161 which the Examiner contends the claimed subject matter is involved. Applicants respectfully disagree with the Examiner's conclusions and submit that claims 1-14 and 16 are nonobvious over the van der Burg patents.

As has been recently instructed by the Federal Circuit:

> "Obviousness based on structural similarity thus can be proved by identification of some motivation that would have led one of ordinary skill in the art to select and then modify a known compound (i.e., a lead compound) in a particular way to achieve the claimed compound... Thus, in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to select and modify a known compound, i.e., a lead compound, in a particular manner to establish prima facie obviousness of a new claimed compound...In other words, post-KSR , a prima facie case of obviousness for a chemical compound still, in general, begins with the reasoned identification of a lead compound." Eisai

Co., Ltd v. Dr. Reddys Laboratories, Ltd. and Teva Pharmaceuticals USA (Fed. Circuit, decided July 21, 2008 citing Takeda Chem. Indus. v. Alphapharm Pty., Ltd, 492 F. 3d 1350, 1356, Fed. Cir. 2007, 492, F. 3d at 1357).

It is submitted that the Examiner has not identified a reason that would have led a chemist to select and modify a known compound in the van der Burg patents to arrive at the compound recited in claim 1.

In contrast to the Examiner's statement that the generic structure described/claimed in the van der Burg patents encompasses the presently claimed compounds, the van der Burg patents make clear that the –(CH2)n-NR5R6 moiety is present only at positions 2 or 3 of the compound of formula (I) (see USP 4,054,572, column 1, lines 30-36 and USP 4,016,181, column 24, lines 37-44), whereas in the presently claimed compound the –(CH2)n-NR5R6 moiety is present only at position 1. Accordingly, the van der Burg generic compound of formula I does not encompass the presently claimed compounds. In addition, there is no teaching or suggestion in van der Burg to modify its compounds to possess the –(CH2)n-NR5R6 moiety at position 1, nor is there any description in van der Burg of how to make compounds having the –(CH2)n-NR5R6 moiety at position 1 wherein the bridgehead H and N are on the same side of the ring as set forth for the presently claimed compound of formula I.

With respect to the Examiner's contention that "The position of the moiety in van der Burg possesses the same level of activity as shown by the variability of the moiety on the piperidine ring of the tetracyclic ring system such that the moiety is substituted at the 2-position or 3-position of the ring system", the activity described for the van der Burg compounds is **antidepressant activity** (see e.g., U.S. Patent 4,054,572, column 9, lines 52-62), and **not** progestagenic activity. There is no teaching or any suggestion whatsoever that the van der Burg compounds having at position 2 or 3 a –(CH2)n-NR5R6 moiety would also possess progestagenic activity. Accordingly, with no teaching or suggestion that the van der Burg compounds possess progestagenic activity, there is no reason that would have led a chemist skilled in the art to modify the van der Burg compounds selected by the Examiner in the manner stated by the Examiner to arrive at the presently claimed compounds having progestagenic activity. Indeed, no reason is provided in the van der Burg patents to select

from the greater than 80 described compounds the few 2-dimethylamino...oxazepine compounds described in van der Burg for modification to compounds having at the 1-position a –(CH2)n-NR5R6 moiety for the purpose of providing progestagenic activity. Accordingly, since there is no reason for a chemist to select the specific 2-dimethylamino...oxazepine compounds out of all the compounds described in van der Burg and then modify such compounds to possess a –(CH2)n-NR5R6 moiety at position 1 for the purpose of having progestagenic activity, the claimed compounds are not rendered obvious by the van der Burg patents.

In view of the above, withdrawal of the rejection of claim 1-14 and 16 under 35 U.S.C. §103(a) is respectfully requested.

Claims 1-14 and 16 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 and 21 of copending application no. 11/861,427. The Examiner contends that while the conflicting claims are not identical, they are not patentably distinct from each other because the compound of the instant invention embraces the compounds of formula I of copending application no. 11/861,427 where R1 is H,; R2 is F; R3 is CN; R4 is H; R8 is H; R9 is H, R7 is H and R6 is C(O)-(1-4C) alkyl optionally substituted with one or more halogen atoms.

In response, Applicants request that this rejection be held in abeyance until indication by the Examiner that the pending claims are otherwise allowable.

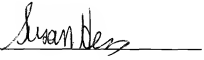
Claims 1-14 and 16 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending application no. 12/115,983. The Examiner contends that while the conflicting claims are not identical, they are not patentably distinct from each other because the compound of the instant invention embraces the compounds of formula I of copending application no. 12/115,983 where R1 is H; R4 is H; R8 is H; R9 is H, R7 is H and R6 is (1-5C)acyl, (1-5)thioacyl, (1-4C)alkylsulfonyl and (1-4C)alkoxycarbonyl, each optionally substituted with one or more halogen atoms.

In response, Applicants request that this rejection be held in abeyance until indication by the Examiner that the pending claims are otherwise allowable.

A good faith effort has been made to place the present application in condition for allowance. If the Examiner believes a telephone conference would be of value, she is requested to call the undersigned at the number listed below.

Dated: December 11, 2008

Respectfully submitted,

By 

Organon International Inc.
Patent Department
c/o Schering-Plough Corporation
2000 Galloping Hill Road
Kenilworth, New Jersey 07033-0530
K-6-1; MS 1990
Tel: (908) 298-2161
Fax: (908)-298-5388

Susan Hess
Registration No.: 37,350
Attorney For Applicant(s)

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